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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,482	09/15/2000	Linda Anne Crofts	1871-130	9624

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EXAMINER	
ULM, JOHN D	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/509,482	Crofts
Examiner	**Art Unit**
John Ulm	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 28, 2003* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above, claim(s) *5-8, 15-20, 25, and 26* is/are withdrawn from consideration.

5) ☒ Claim(s) *24* is/are allowed.

6) ☒ Claim(s) *1-4, 9-14, 21-23, 27, and 29* is/are rejected.

7) ☒ Claim(s) *28* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 12
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1) Claims 1 to 29 are pending in the instant application. Claims 1 to 4, 9 to 14 and 21 to 24 have been amended and claims 26 to 29 have been added as requested by Applicant in Paper Number 18, filed 28 January of 2003.

2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claims 5 to 8, 15 to 20, 25 and 26, as well as claims 1 to 5, 9 to 14 and 21 to 24 in so far as they are drawn to complementary nucleic acids, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8. Applicant is advised that claim 26 can not properly depend from claim 1 because claim 26 can be infringed by an isolated polynucleotide that does not infringe claim 1. See M.P.E.P. 608.01(n)III.

5) The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 28 January of 2003 have been approved. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

6) Claim 24 is allowable as written.

7) Claim 28 is objected to because it does not comply with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. Claim 26 refers to a specific amino acid sequence without employing a sequence identifier. This claim would otherwise be allowable. Correction is required. See M.P.E.P. 2422.03.

8) Claims 1 to 4 and 9 to 14 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention essentially for those reasons of record in section 9 of Paper number 10. These claims encompass a polynucleotide molecule encoding a human vitamin D receptor isoform and comprising a nucleotide sequence at least 95% identical to "a nucleotide sequence of exon 1d of human VDR gene, or fragment thereof". The only "nucleotide sequence of exon 1d of human VDR gene" which is described in the instant specification in sufficient detail to demonstrate possession is presented in SEQ ID NO:1 of the instant application. One of ordinary skill in the art of molecular biology would not believe that the majority of nucleotide sequences having at least 95% sequence identity to SEQ ID NO:1 would correspond to a naturally occurring "nucleotide sequence of exon 1d of human VDR gene" and the instant specification fails to identify that feature or combination of features which distinguishes "a nucleotide sequence of exon 1d of human VDR gene" from any other nucleic acid sequence.

Therefore, the instant specification fails to provide an adequate written description of the genus of polynucleotides encompassed by the instant claims.

Further, claim 1 encompasses an isolated polynucleotide molecule encoding a human vitamin D receptor isoform and comprising a fragment of "a nucleotide sequence of exon 1d of human VDR gene". A fragment of a nucleotide can consist of as little as a single base. Because all four nucleotide bases are present in SEQ ID NO:1, the limitation "a nucleotide sequence of exon 1d of human VDR gene, or fragment thereof" has no weight because any polynucleotide is going to inherently comprise a fragment of "a nucleotide sequence of exon 1d of human VDR gene". Therefore, claim 1 encompasses any isolated polynucleotide encoding a human vitamin D receptor isoform, irrespective of the sequence of that polynucleotide. The term "human vitamin D receptor" is functionally defined in the art as any protein which binds to vitamin D and induces a physiological response in the cell expressing it as a consequence of that binding. In other words, the term "human vitamin D receptor" is defined solely by function and organism of origin. Any protein is an isoform if it can occur in more than one form and almost all proteins can be found in more than one form. Because the polynucleotide of claim 1, for example, is defined solely by function since it encompasses any isolated polynucleotide encoding any human protein capable of functioning as a vitamin D receptor, it is a single means claim. A single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. In re Hyatt , 708 F.2d 712,>714 - 715,< 218 USPQ 195>, 197< (Fed. Cir. 1983) (A single means claim which covered

every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend on a recited property, a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. See M.P.E.P. 2164.08(a)

9) Claims 1 to 4 and 9 to 14 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention essentially for those reasons of record in section 10 of Paper Number 10. These claims require an isolated polynucleotide which encodes a human vitamin D receptor. The only human proteins capable of functioning as vitamin D receptors that are described in the instant specification in sufficient detail as to enable an artisan of ordinary skill to produce a nucleic acid molecule encoding any one of them without the need to resort to that undue experimentation discussed in the original rejection are those four human proteins whose amino acid sequences are disclosed in SEQ ID NOs:9 to 12 of the instant application. As indicated in the preceding rejection, claim 1 essentially encompasses an isolated polynucleotide encoding any human protein which is capable of functioning as a vitamin D receptor. These claims encompass thousands, if not tens of thousands, of material embodiments of nucleic acid. The instant specification, however, does not provide the guidance needed to manufacture the very broad genus of isolated

nucleic acid molecules encompassed by these claims or even a representative number. Further, as stated in the original rejection, the instant specification does not provide the guidance needed to alter any one of those four amino acid sequence disclosed therein at even a single residue with a reasonable expectation that the resulting protein will function as a vitamin D receptor. Therefore, the instant specification and art of record do not support the breadth of the instant claims.

10) Claims 21 to 23, 27 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention for those reasons of record as applied to claims 21 to 24 in section 11 of Paper Number 10. Applicant has essentially traversed this rejection on the premise that the degeneracy of the genetic code would allow one to alter the referenced nucleotide sequence without affecting its function. Such arguments would be persuasive if the claims were directed to an isolated polynucleotide which was defined solely by an amino acid sequence encoded thereby. However, the vast majority of material embodiments encompassed by the instant claims would not be expected to encode any portion of an amino acid sequence capable of functioning as part of a vitamin D receptor and the instant specification fails to disclose a specific utility for an isolated polynucleotide which is incapable of being employed in a process of producing alternatively spliced forms of a human vitamin D receptor.

11) Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is confusing because of the repeated occurrence of the term "of, of".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12) Claims 1, 2, 10, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by the MacDonald et al. publication (J. Biol. Chem. 266(28):18808-18813, "Baculovirus-mediated Expression of the Human Vitamin D Receptor", 05 Oct. 1991). As indicated in section 8 above, claim 1 encompasses any isolated nucleic acid encoding a human protein capable of functioning as a vitamin D receptor. These claim encompass the expression vector and host cell that was described in the MacDonald et al. publication more than one year before the filing date of the instant application.

13) Applicant's arguments filed 28 January of 2003 have been fully considered but they are not persuasive for those reasons given above.

14) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN ULM
PRIMARY EXAMINER
GROUP 1800